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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,343	10/12/2000	Romualdas Vaisvila	NEB-181	7976

28986 7590 01/29/2003  
NEW ENGLAND BIOLABS, INC.  
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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/689,343

Applicant(s)

VAISVILA ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/12/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other:  |

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### **Detailed Action**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The instant Specification **contains 21 nucleotide and amino acid sequences but only 9 are included** in the Sequence Listing filed 10/08/02.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

The non-compliance with regard to the Sequence Listing has not however, precluded an examination of the application on the merits, the results of which appear below.

The disclosure is objected to because of the following informalities: Blanks appear on pages 16, 25, 55 and 59.

Appropriate correction is required.

Applicant's election without traverse of Group I, claims 1-6 in Paper No. 19 is acknowledged.

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Claims 7-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in Paper No. 19.

It is noted that applicants, in the Response to the Restriction requirement filed 12/24/02, requested that the non-elected claims 7-15 be canceled. However, this request was not in the form of an amendment and the claims are still pending in the application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim isolated DNA encoding any MseI endonuclease and methylase wherein the DNAs are "obtainable" from *Micrococcus species* or ATCC PTA-2421, as well as vectors and host cells containing said DNA and a method of making MseI restriction endonuclease comprising culturing the cells containing said DNA. It is noted that although applicants recite that the MseI DNA is **obtainable from** *Micrococcus species*, or from the ATCC PTA-2421 deposit, the claims do not exclude MseI encoding DNAs obtainable from any other source.

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Since the claims are not limited to DNAs encoding MseI from *Micrococcus species* or ATCC PTA-2421, they read on a genus of DNAs encoding MseI from any source. Applicants provide a written description of the MseI restriction endonuclease from *Micrococcus species* (NEB#446).

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus. In the instant case, applicants provide one example of a DNA encoding a MseI restriction endonuclease from *Micrococcus species* NEB#446. Applicants do not disclose and the prior art does not provide a correlation between the function of the MseI restriction endonuclease and its structure. Given that the claims read on DNA encoding MseI from any source, given the lack of a correlation between the structure of the enzyme and its functions and given the one example provided by applicants, it must be concluded that the one disclosed example is not a representative number of species sufficient to describe the claimed genus and the skilled artisan would therefore not conclude that applicants were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 (and dependent claims) are vague in that there is no antecedent for the term "the MseI restriction endonuclease".

Claim 1 is vague in that applicants a MseI encoding DNA obtainable from "*Micrococcus species*". It is unclear what *Micrococcus species* is being referred to, i.e. any *Micrococcus species* or *Micrococcus species* NEB#446?

Claims 1 and 3 are vague because the claims do not begin with an article such as "The" or "A" or "An", etc.

Claim 5 is vague because there is no antecedent basis for the term "the cloning vector" in claim 2.

The closest prior art is represented by Morgan (Nucleic Acids Res., Vol. 16, No. 7, 1988, cited by applicants). Morgan does not teach the DNA encoding any MseI restriction endonuclease.

No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
January 21, 2003

DAVID GUZO  
PRIMARY EXAMINER  
